



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S.

Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of patent applications may be obtained by emailing Brian W. Bailey, PhD, bbailey@mail.nih.gov, the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Use of statins to treat or prevent drug-induced hearing loss

Description of Technology:

Available for licensing and commercial development are patent rights covering methods of using atorvastatin and related statin compounds and derivatives to reduce or prevent drug-induced hearing loss that is caused as a side effect by ototoxic drugs such as cisplatin, which is commonly used in cancer therapies. At present, permanent hearing loss occurs in approximately half of all patients treated with cisplatin; consequently, every year many thousands of individuals experience partial loss of hearing and

associated quality of life issues as a result of medically necessary chemoradiation therapies to treat their cancers. This technology addresses a large unmet need to eliminate or reduce hearing loss in patients that must undergo therapies involving ototoxic drugs.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- Repurposing existing statins, including atorvastatin, to treat or protect against permanent hearing loss arising from chemoradiation therapy involving ototoxic drugs
- Development of statin analogues or derivatives with enhanced abilities to treat or protect against hearing loss resulting from therapies involving cisplatin or other ototoxic drugs

Competitive Advantages:

- This invention addresses an urgent need to protect against permanent hearing loss resulting from therapies with commonly used but ototoxic drugs, including cisplatin.
- Statins are already extensively used therapeutically to lower blood cholesterol and have well understood drug profiles, making them ideal candidates for repurposing.

Development Stage: An observational clinical trial (NCT03225157) in patients with head and neck cancers has been completed.

Inventors: Lisa Lynn Cunningham (NIDCD), Nicole C. Schmitt (NIDCD), and Katharine Ann Fernandez (NIDCD)

Publications: J Clin Invest. 2021;131(1):e142616

Intellectual Property: HHS Reference No. E-029-2020 – PCT/US21/14918 filed January 25, 2021; U.S. Patent Application No. 62/966,794 filed January 28, 2020.

Licensing Contact: Brian W. Bailey, PhD; 301-594-4094; bbailey@mail.nih.gov.

Bruce D. Goldstein,

Director, National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development,

National Institutes of Health.

[FR Doc. 2021-04069 Filed: 2/26/2021 8:45 am; Publication Date: 3/1/2021]